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| EXAMINER | |
|---|---|
| ANDERSON, REBECCA L | |
| ART UNIT | PAPER NUMBER |
| 1626 | |

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/914,884 | BEATCH ET AL. | |
| | Examiner | Art Unit | |
| | Rebecca L Anderson | 1626 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *04 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3, 5-7, 38-47, 72-75 and 84-114* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3, 5-7, 38-47, 72-75 and 84-114* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-3, 5-7, 38-47, 72-75 and 84-114 are currently pending in the instant application. The rejections of the office action mailed 4 November 2003 are withdrawn in view of the following new lack of unity requirement. Claims 1-, 5-7, 38-47, 72-75 and 84-114 are subject to the following lack of unity requirement.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous and widely divergent variable in the compound of the formula (I), for example, X, Y, R13, R1, R2, R3, R4, R5, R6, R14, A, R7, R8, R9, R10, R11, R12, Z, etc., and the numerous provisos, a precise listing of inventive groups cannot be made. The following groups are exemplary:

***Group I***: Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 drawn to products of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are independently selected from hydrogen, C1-C8alkyl, C3-C8 alkoxyalkyl, C1-C8 hydroxyalkyl and C7-C12 aralkyl, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group II***: Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 drawn to products of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group III***: Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 drawn to products of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a bicyclic ring system of 3-azabicyclo[3.2.2]nonan-3-yl, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group IV***: Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 drawn to products of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a bicyclic ring system of 2-azabicyclo[2.2.2]octan-2-yl, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy

and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group V***: Claims 1-3, 38, 40, 42, 44, 46, 72, 74, 84, 90-92, 105, 108 and 114 drawn to products of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to forma bicyclic ring system of 3-azabicyclo[3.1.0]hexan-3-yl, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group VI***: Claims 5 and 109 drawn to a method for treating arrhythmia and providng therapy for arrhythmia by administering a compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group VII***: Claims 6, 7 drawn to a method for modulating ion channel activity with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen,

hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group VIII***: Claim 39 drawn to a method for treating a cardiovascular disease with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group IX***: Claim 41 drawn to a method of treating cerebral or myocardial ischemias with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group X***: Claim 43 drawn to a method of treating hypertension with a compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring,

R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XI***: Claim 45 drawn to a method for treating long-QT syndrome with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XII***: Claim 47 drawn to a method for treating a stroke with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XIII***: Claim 73 drawn to a method of producing local analgesia or anesthesia with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-

C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XIV***: Claim 75 drawn to a method for treating heart failure with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XV***: Claim 85 drawn to a method of enhancing libido with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XVI***: Claims 86 and 99 drawn to a method for providing therapy for and treating atrial arrhythmia with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is

hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XVII***: Claims 87 and 101 drawn to a method for providing therapy for and treating ventricular arrhythmia with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XVIII***: Claim 88 drawn to a method for treating atrial fibrillation with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XIX***: Claim 89 drawn to the method of treating ventricular fibrillation with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and

benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XX***: Claims 93-95 drawn to a method of blocking an ion channel with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

Group XXI: Claim 96 drawn to a method of preventing arrhythmia with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXII***: Claim 97 drawn to the method for preventing cerebral or myocardial ischemias with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-

C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXIII***: Claim 98 drawn to the method for preventing heart failure with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXIV***: Claim 100 drawn to a method of preventing atrial arrhythmia with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXV***: Claim 102 drawn to a method of preventing ventricular arrhythmia with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and

benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXVI***: Claim 103 drawn to a method of preventing atrial fibrillation with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXVII***: Claim 104 drawn to a method of preventing ventricular fibrillation with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXVIII***: Claim 106 drawn to a method of treating depression with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy,

C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXIX***: Claim 107 drawn to a method of preventing depression with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXX***: Claim 110 drawn to a method of preventing hypertension with the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXXI***: Claim 111 drawn to a method of preventing long-QT syndrome with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and

benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

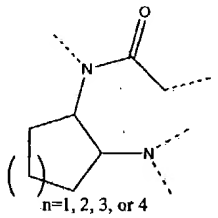
***Group XXXII***: Claim 112 drawn to a method of preventing stroke with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

***Group XXXIII***: Claim 113 drawn to a method of preventing a cardiovascular disease with the compound of the formula (I) wherein n is as found in claim 1, X is a direct bond, Y is a direct bond, R13 is as found in claim 1, R1 and R2 are taken together with the nitrogen atom to which they are directly attached in formula (I) to form a morpholinyl ring, R3 and R4 are independently selected from hydrogen, hydroxy, C1-C6alkyl and C1-C6 alkoxy and R5 is hydrogen, C1-C6alkyl, aryl and benzyl, A is C5-C12 alkyl, C3-C13 carbocyclic ring or the ring system of formulae (III).

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. Again, this list is not exhaustive as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention (a product, or a method of use) by identifying another specific embodiment not listed in the exemplary groups of the

invention and examiner will endeavor to group the same. The applicant may also choose to elect a single disclosed species and the examiner will endeavor to create a group comprising the elected species.

The claims herein lack unity of invention under PCT rule 13.1 and 13.2 since, under 37 CFR 1.475(a) the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain 2-amino cycloalkyl amide,




, which does not define a contribution over the prior art (as can be seen by formula (I) in column 2 of the US Patent No. 5, 506,257 entitled aminocyclohexylamides for antiarrhythmic and anaesthetic uses). The variables on the 2-amino cycloalkyl amide vary extensively and when taken as a whole result in vastly different compounds. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Furthermore, even if unity of invention under 37 CFR 1.475(a) is not considered to be lacking, which it is considered to be lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of

invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and a process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

And, according to 37 CFR 1.475(c)

if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

Therefore, since the claims are drawn to more than a product and more than a method of use, and according to 37 CFR 1.475 (e)

the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

The claims lack unity of invention and should be limited to only a product or a use of the said product.

## Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rebecca Anderson
Patent Examiner
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